IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA and REGENXBIO INC., Plaintiffs, v. SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC, Defendants.	C.A. No. 20-1226 (RGA) **JURY TRIAL DEMAND**

PLAINTIFF REGENXBIO INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR CERTIFICATION FOR INTERLOCUTORY APPEAL

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Dated: February 7, 2022

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Interlocutory appeals are proper only under exceptional circumstances, and Sarepta has failed to present such circumstances here. Instead, Sarepta is merely dissatisfied with this Court's ruling, and wants a second bite at the apple before a different forum. Courts have routinely cautioned that certification for interlocutory review should be used sparingly, and here the question Sarepta poses for interlocutory review has been addressed by the Federal Circuit and numerous district courts. Accordingly, Sarepta's request for certification should be denied.

I. NATURE AND STAGE OF THE PROCEEDING

On September 15, 2020, Plaintiffs REGENXBIO Inc. ("REGENXBIO") and The Trustees of The University of Pennsylvania ("The University") (collectively, "Plaintiffs"), filed a Complaint for patent infringement of U.S. Patent No. 10,526,617 ("the '617 Patent") by Defendants Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC (collectively, "Sarepta"). *See* Compl. (D.I. 1). Plaintiffs' Complaint alleges that Sarepta uses the cultured host cells claimed in the '617 Patent to manufacture its recombinant adeno-associated virus ("AAV") gene therapy products, including at least SRP-9001 and SRP-9003. *See id.* ¶¶ 26-37. Although Sarepta's gene therapy products require FDA approval for marketing, the cultured host cells claimed in the '617 Patent, and used by Sarepta to produce its gene therapy products, do not. *See id.* ¶ 34.

On November 4, 2020, Sarepta moved this Court to dismiss the Complaint, alleging that its use of the cultured host cells claimed in the '617 Patent is protected from liability for infringement by the Safe Harbor of 35 U.S.C. § 271(e)(1). *See* D.I. 12, 13. Plaintiffs opposed Sarepta's motion to dismiss, with REGENXBIO asserting that Sarepta's infringement was not protected by the Safe Harbor in view of the Federal Circuit's holding in *Proveris Sci. Corp. v. Innovasystems, Inc*., 536 F.3d 1256, 1265-66 (Fed. Cir. 2008), and both Plaintiffs further arguing

that factual disputes with regard to Sarepta's commercial activities precluded dismissal of the Complaint. *See* D.I. 20, 22.

On December 20, 2021, the Court heard oral argument on Sarepta's motion to dismiss. On January 4, 2022, the Court denied Sarepta's motion, finding that Sarepta had failed to demonstrate that the facts alleged in the Complaint establish that the infringing activity is exempted by the Section 271(e)(1) Safe Harbor. *See* D.I. 36 at 9.[1]

II. SUMMARY OF THE ARGUMENT

Sarepta fails to meet the standard for certification of a question for interlocutory appeal. Rather than present a controlling question of law that will materially advance the termination of this lawsuit, Sarepta merely disagrees with the outcome of the Safe Harbor issue that the Court resolved based on well-settled and consistently applied case law.

1. Sarepta fails to present a controlling question of law. How "patented invention" is defined for purposes of the 35 U.S.C. § 271(e)(1) Safe Harbor was squarely addressed in *Proveris*, which found "patented inventions" are only those that are themselves subject to FDA premarket approval. 536 F.3d at 1265-66. This Court and several other districts have consistently applied this holding of *Proveris*. Moreover, Sarepta's contention that it presents a controlling question of law that will fully resolve the disputed issues in this case is incorrect, as Plaintiffs' commercial activities argument will still need to be addressed even if the Federal Circuit were to resolve the Safe Harbor issue in Sarepta's favor.

[1] In a footnote, Sarepta notes that REGENXBIO announced that it intends to make a gene therapy product to treat Duchenne muscular dystrophy. D.I. 41 at 4 n.2. That is of no moment to the instant case, as REGENXBIO's product, like Sarepta's SRP-9001 product, is not covered by the '617 Patent. And it does not change the Court's correct finding that Sarepta is not attempting to "introduce generic cultured host cells to compete in the marketplace when the '617 patent expires." D.I. 36 at 9.

2. Sarepta fails to demonstrate any substantial ground for difference of opinion, and skews the relevant case law to manufacture the appearance of a split between district courts applying the Safe Harbor. Contrary to the picture Sarepta paints, the Federal Circuit and district courts have consistently held that if the "patented invention" requires FDA premarket approval, then the Safe Harbor applies. By contrast, if the "patented invention" does not require FDA premarket approval, then the Safe Harbor does not apply. *See, e.g.*, *PSN Ill., LLC. v. Abbott Labs*., No. 09cv5879, 2011 U.S. Dist. LEXIS 108055, at *18 (N.D. Ill. Sept. 20, 2011); *ISIS Pharms., Inc. v. Santaris Pharma A/S Corp*., No. 11cv02214 BTM (KSC), 2012 U.S. Dist. LEXIS 134107, at *11 (S.D. Cal. Sept. 18, 2012); *Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc.*, No. 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347, at *11 (S.D. Cal. May 4, 2021). This straightforward application of the Safe Harbor was also followed in *UCB, Inc. v. Catalent Pharma Sols., Inc*., a case which Sarepta raises for the first time in its Motion, but misreads in an attempt to support its manufactured split in judicial opinion. No. 5:21-cv-00038-GFVT, 2021 U.S. Dist. LEXIS 90623 (E.D. Ky. May 12, 2021). As discussed below, this decision supports REGENXBIO's—not Sarepta's—position. The lone outlier case on which Sarepta relies, *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 09-Civ.-10112(KBF), 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013), contains a strained reading of *Proveris*, leading this Court and others to find it unpersuasive or wrongly decided. That sole decision cannot reasonably support Sarepta's alleged substantial ground for difference of opinion.

3. Sarepta fails to show that its appeal will materially advance the ultimate termination of this suit, and it has not demonstrated why this case is exceptional, warranting a significant departure from the normal litigation process. Further, Sarepta ignores the fact that Plaintiffs' commercial activities argument will need to be addressed even if Sarepta is successful in its

interlocutory appeal. This, in turn, will complicate the procedure of this case and drain the resources of all parties and the Court.

III. STATEMENT OF FACTS

A. The Court's January 4 Order

The Court's January 4 Order denying Sarepta's motion to dismiss found that "since the patented cultured host cells are not subject to FDA regulatory approval, they are not a 'patented invention' under § 271(e)(1)." *See* D.I. 36 at 8-9. That finding is consistent with cases from the Federal Circuit and various district courts addressing this issue. That Sarepta is unsatisfied with the holding of the January 4 Order does not justify certification for interlocutory appeal.

B. The Consistently Applied Law on the Safe Harbor

While Sarepta attempts to portray cases addressing which inventions are entitled to protection under the Safe Harbor as divided, prior courts deciding this and related issues have consistently applied the protections of and exceptions to the Safe Harbor. Specifically, if the patented product is itself subject to FDA regulatory approval, then the protections of the Safe Harbor apply. If not, then the Safe Harbor is inapplicable.

In *Eli Lilly & Co. v. Medtronic, Inc*., the Supreme Court decided whether the Safe Harbor covers medical devices in addition to drug products. 496 U.S. 661 (1990). In finding that it does, the Court held that "[t]he phrase 'patented invention' in 271(e)(1) is defined to include all inventions, not drug-related inventions alone." *Id.* at 665. To reach this holding, the Court explained how 35 U.S.C. §§ 156 (patent term extension provision) and 271(e)(1) were enacted in order to eliminate two unintended distortions of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA. *Id.* at 669-670. Like drug products, the medical devices at issue in *Eli Lilly* required FDA regulatory approval and thus were covered by the Safe Harbor. *See id.* Several years later in *AbTox, Inc. v. Exitron Corp.*, the Federal Circuit

clarified the breadth of the protections afforded by the Safe Harbor. 122 F.3d 1019 (Fed. Cir. 1997). The accused device in *AbTox* was a Class II medical device that required an abbreviated FDA approval process, and the court determined that its use was protected by the Safe Harbor even though, as a Class II medical device, it was ineligible for a patent term extension under Section 156. *Id.* at 1027. By following *Eli Lilly*, the court recognized that the Supreme Court found the term "patented invention" in Section 271(e)(1) included "any medical device." *Id.* at 1028.

Over a decade later, in *Proveris Sci. Corp. v. Innovasystems, Inc*., the Federal Circuit again addressed the scope of the Safe Harbor's protections. 536 F.3d at 1256. In *Proveris*, the asserted patent was directed to a system and apparatus for characterizing aerosol sprays commonly used in testing of various drug-delivery devices. *Id.* at 1258. While the devices were used to generate data for FDA approval, the system and apparatus claimed in the patent were "not themselves subject to FDA approval," and thus the court found that the apparatus at issue was not a "patented invention" within the scope of the Section 271(e)(1) Safe Harbor. *Id.* at 1258, 1265-66. More specifically, "[b]ecause Proveris's patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. 156(f). At the same time, because Innova's OSA device is also not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. 271(e)(1)." *Id.* at 1265-66.

District courts following *Proveris* have reached similar conclusions when addressing the Safe Harbor and its applicability to products not themselves subject to regulatory approval. For example, in *PSN Ill., LLC. v. Abbott Labs*., the patents-in-suit related to receptors that Abbott used to develop drug candidates. 2011 U.S. Dist. LEXIS 108055, at *3-6. The patented receptors were used by defendant Abbott to obtain a therapeutic agent. *Id*. In holding that the Safe Harbor did

not apply, the court relied on *Proveris*, *Proveris's* analysis of *Eli Lilly*, and the statutory intent behind Section 271(e)(1). *Id*. *9-11. Accordingly, since the patented receptors were not subject to FDA approval, and "[defendants] were using [them] to develop their own" product, the receptors were not a "patented invention" within the meaning of Section 271(e)(1), and the Safe Harbor did not apply. *Id*. at *18. Similarly, in *ISIS Pharms., Inc. v. Santaris Pharma A/S Corp*., the asserted patents covered antisense technology that the defendant used to contact cells in culture to "identify gene targets." 2012 U.S. Dist. LEXIS 134107, at *11-14. The court quoted *Proveris* in stating that "'research tools' are patented inventions that are 'used in the development of . . . regulatory submissions but [are] not [themselves] subject to the [regulatory approval] process.'" *Id.* at *11. Because the patented product was not itself subject to regulatory approval, the court found the Safe Harbor did not apply and denied summary judgment of non-infringement. *Id.* at *14.

The same reasoning was later applied in *Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc*., where the asserted patent covered a fluorescent protein used as a biological tag in genetic engineering work. 2021 U.S. Dist. LEXIS 85347, at *2. In denying the motion to dismiss, the court analyzed *Proveris* and held that the invention claimed in the asserted patent was not "a 'patented invention' for the purposes of section 271(e)(1)" because the patented fluorescent protein was not "subject to review by the FDA," therefore, the Safe Harbor did not apply. *Id.* at *11, *18.

The court in *UCB, Inc. v. Catalent Pharma Sols., Inc*., a decision which Sarepta raises for the first time in its Motion, is fully consistent with these cases. 2021 U.S. Dist. LEXIS 90623. There, the asserted patent covered a chemical compound that was an active pharmaceutical ingredient in the plaintiff's FDA-approved drug product. *Id.* at *2. Since the patented product was itself subject to FDA regulatory approval, the Safe Harbor applied to immunize the defendant from infringement. *Id.* at *9. The court correctly distinguished *Proveris*, pointing out how the

patented invention in *Proveris* was "not subject to the premarket approval required by the FDCA," and thus the Safe Harbor did not apply. *Id.* at *6-7.

The only case that does not follow this consistent line of precedent is *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 2013 U.S. Dist. LEXIS 99121. Rather than follow each of the other cases addressing the issue, the *Teva* court engaged in a strained reading of *Proveris*, and found that what the *Proveris* court "could just as easily" have found was that "it was those uses to which the defendant was putting the patented devices that was objectionable." *Id*. at *8. As a result, several courts, including this one, have rejected the reasoning of *Teva*. *See* D.I. 36 at *7-8; *Allele*, 2021 U.S. Dist. LEXIS 85347, at *16-17 ("As such, the Court does not find *Teva's* analysis of *Proveris* persuasive."); *ISIS Pharms., Inc. v. Santaris Pharma A/S Corp.*, No. 3:11-CV-2214-GPC-KSC, 2014 U.S. Dist. LEXIS 26148, at *33 n.7 (S.D. Cal. Feb. 27, 2014) ("Having considered *Teva*, this Court disagrees with its limited reading of *Proveris* and its complete rejection of *PSN Illinois*.").

Aside from *Teva v. Sandoz*, which has repeatedly been found to be a wrongly-decided outlier, each of the cases consistently apply the Safe Harbor to find that patented products that require FDA premarket approval fall within its protection, while products that do not require FDA premarket approval do not.

IV. ARGUMENT

"Leave to file an interlocutory appeal may be granted when the order at issue (1) involves a controlling question of law upon which there is (2) substantial grounds for difference of opinion as to its correctness, and (3) if appealed immediately, may materially advance the ultimate termination of the litigation." *Microsoft Mobile, Inc. v. Interdigital, Inc*., No. 15-723-RGA, 2016 U.S. Dist. LEXIS 76367, at *2-3 (D. Del. June 13, 2016) (Andrews, J.) (quoting *In re SemCrude, L.P.*, 407 B.R. 553, 556-57 (D. Del. 2009)); 28 U.S.C. § 1292(b). "Interlocutory appeal is meant to be used sparingly and only in exceptional cases where the interests cutting in favor of immediate

appeal overcome the presumption against piecemeal litigation." *Id.* at *3 (quoting *DeLalla v. Hanover Ins*., 2010 U.S. Dist. LEXIS 104323, at *3 (D.N.J. Sept. 30, 2010)) (emphasis added). "Further, leave for interlocutory appeal may be denied for 'entirely unrelated reasons such as the state of the appellate docket or the desire to have a full record before considering the disputed legal issue.'" *In re BSA*, No. 20-774-RGA, 2021 U.S. Dist. LEXIS 58837, at *13 (D. Del. Mar. 29, 2021) (Andrews, J.) (quoting *Katz v. Carte Blanche Corp*., 496 F.2d 747, 754 (3d Cir. 1974)).[2]

A. The January 4 Order Does Not Involve a Controlling Question of Law

As described above, courts that have interpreted what a "patented invention" is within the scope of the 35 U.S.C. § 271(e)(1) Safe Harbor have consistently found that "patented inventions" protected by the Safe Harbor are only those that require FDA premarket approval. The Federal Circuit in *Proveris* was presented with this very issue—whether the use of a patented invention not itself subject to FDA premarket approval was nonetheless protected by the Safe Harbor. 536 F.3d at 1265. The *Proveris* court held that the Safe Harbor does not protect such inventions that do not require FDA premarket approval. *Id.* This same question has been addressed by several district courts since *Proveris*, and they have consistently applied the reasoning and holding of *Proveris*, just as this Court did here. *See, e.g.*, Section II.B., *supra*. Sarepta fails to present a

[2] Sarepta's Motion for certification for interlocutory appeal may also be untimely under the interpretation of the statutory timing requirements in this district. Specifically, 28 U.S.C. § 1292(b) states in pertinent part, "[t]he Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order." This Court's order denying Sarepta's motion to dismiss issued on January 4, 2021, and Sarepta moved for certification for interlocutory appeal twenty days later, on January 24, 2021. *See, e.g.*, *Chase Manhattan Bank v. Iridium Afr. Corp*., 324 F. Supp. 2d 540, 545 (D. Del. 2004) ("As an initial matter, the Court concludes that Defendants' application for an interlocutory appeal of the February 13 Opinion was not filed within the time limitation imposed by 28 U.S.C. § 1292(b), and therefore, must be denied. Defendants filed their Motion for Interlocutory Appeal of the February 13 Opinion on March 16, 2004, clearly beyond the ten (10) day application period provided by 28 U.S.C. § 1292(b).").

controlling question of law to the Court, but rather presents a question that has been well-settled in over a decade of jurisprudence.[3]

Sarepta further asserts that the question of law it presents is controlling because appellate reversal on the Safe Harbor dispute would allegedly require dismissal of this lawsuit. Mot. at 8-9. Not so. As Sarepta correctly notes in its Motion, the Court did not address Plaintiffs' argument regarding Sarepta's commercial activities involving the patented invention at the motion to dismiss stage. *See id.* In finding that dismissal of the Complaint was not appropriate based on REGENXBIO's primary argument regarding the Safe Harbor, the Court did not reach Plaintiffs' commercial activities allegations. As a result, even if Sarepta were successful in this appeal, dismissal of the lawsuit would not follow. Sarepta attempts to diminish the significance of Plaintiffs' commercial activities argument. This Court, however, has previously determined in another matter that Sarepta's activities concerning SRP-9001—the product that Sarepta is using Plaintiffs' patented cultured host cells to manufacture—include "the manufacture of certain drug batches unrelated to its FDA submissions," and thus "such activity would not be immunized by the Safe Harbor." *Wilson Wolf Mfg. Corp. v. Sarepta Therapeutics, Inc.*, No. 19-2316-RGA, 2020

[3] Sarepta appears to make a new argument not previously presented in its motion to dismiss, contesting Plaintiffs' allegation that the patented cultured host cells do not require FDA regulatory approval. *See* Mot. at 2 n.1. Not only is this contention incorrect, it is also irrelevant. At the motion to dismiss stage, all facts are resolved in Plaintiffs' favor. In their Complaint, Plaintiffs explained that the patented cultured host cells are not subject to FDA regulatory approval. *See, e.g.*, Compl. (D.I. 1) ¶ 34. Accordingly, the Court must accept these allegations as true. Moreover, Sarepta's attempt is a red herring, asking this Court to revisit an issue that was already decided by the Supreme Court in *Eli Lilly* and by the Federal Circuit in *Proveris*—namely that "patented invention" of Section 271(e)(1) is defined by Section 156(f) as a drug product (*i.e.*, "active ingredient of a new drug, antibiotic drug, or human biological product"), a "medical device, food additive, or color additive." *See* 35 U.S.C. § 156(f). In contrast, the cultured host cells claimed in the '617 Patent are none of those. Indeed, the patented cultured host cells are consumed in the process of making Sarepta's SRP-9001 product—they are not the SRP-9001 product themselves. *See* Compl. (D.I. 1) ¶ 30; Dec. 20, 2021 Hr'g Tr. at 34:8-15.

U.S. Dist. LEXIS 244122, at *15 (D. Del. Dec. 30, 2020), *report and recommendations adopted*, D.I. 31 (Feb. 2, 2021) (Andrews, J.). Of course, if the Federal Circuit agrees with this Court's ruling on Sarepta's motion to dismiss and follows the controlling precedent on this issue, then Sarepta's appeal would merely be a waste of time and resources for all parties involved. *See In re BSA*, 2021 U.S. Dist. LEXIS 58837, at *17-18 ("Denial of a motion for leave to appeal is appropriate if an immediate appeal of one or all of the issues would only promote piecemeal determination of the questions raised in the adversary action and would likely create unnecessary delay.").

Finally, Sarepta's argument that the district court in *AbTox* certified the Safe Harbor question before it for interlocutory appeal is irrelevant here. Mot. at 9. Not only was the Safe Harbor question in *AbTox* certified for appeal nearly twenty-seven years ago, before any of the cases discussed above except *Eli Lilly* were decided, but also the issue in *AbTox* involved a distinct question—whether all medical devices were subject to Safe Harbor protection. *See Abtox, Inc. v. Exitron Corp.*, 888 F. Supp. 6, 9 (D. Mass. 1995). The law has significantly developed over the past twenty-seven years, and as such the interlocutory appeal on the Safe Harbor question in that case is irrelevant.

B. There is No Substantial Ground for Difference of Opinion

Sarepta attempts to create a split in judicial opinion between different districts on the scope and applicability of the Safe Harbor where no such divide exists. Mot. at 10-13.[4] However, as discussed above in Section II.B., there is a consistent line drawn by the cases assessing the applicability of the Safe Harbor—if the "patented invention" requires FDA premarket approval,

[4] Sarepta's citation to this Court's January 4 Order as an acknowledgement of a split among district courts is misleading and wrong. *See* Mot. at 10 (citing D.I. 36 at 6-8). These pages of the Court's January 4 Order merely recapitulate Sarepta's distorted view of the case law and alleged split in decisions, and Sarepta's analysis was subsequently rejected by the Court. *See* D.I. 36 at 7-8.

then the Safe Harbor applies. If the "patented invention" does not require FDA premarket approval, then it does not. In fact, the cases that this Court found convincing and relied on in denying Sarepta's motion to dismiss all follow this same line of reasoning. *See, e.g.*, *PSN Ill.*, 2011 U.S. Dist. LEXIS 108055, at *18; *ISIS Pharms.*, 2012 U.S. Dist. LEXIS 134107, at *11; *Allele*, 2021 U.S. Dist. LEXIS 85347, at *11; *see also* D.I. 36 at 6. Even *UCB*, a case which Sarepta alleges departs from this sound reasoning, is actually consistent with the earlier cases and supports REGENXBIO's—not Sarepta's—position.[5] *See UCB*, 2021 U.S. Dist. LEXIS 90623, at *9 (holding that the Safe Harbor applied to defendant's actions where the patented invention, a pharmaceutical active ingredient, was subject to FDA regulatory approval).

Once again, the only case inconsistent with the overwhelming precedent is *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121, which this Court and other districts have concluded was unpersuasive or wrongly decided. *See* D.I. 36 at 7 ("I do not find the district court's reasoning in *Teva* persuasive. . . . I conclude that the *Teva* court's limited reading of *Proveris* is not supported by the language in the case, which the district court seems to acknowledge."). As this Court correctly recognized, the district court in *Teva* rewrote what that court believed the holding of *Proveris* should have been in order to reach its conclusion. *See Teva*, 2013 U.S. Dist. LEXIS 99121, at *24 ("[T]he Federal Circuit could just as easily, and perhaps it would have been clearer, to have referred to the language 'solely for uses' as it was those uses to which the defendant was putting the patented devices that was objectionable (selling them to others and not itself actually developing any information for submission)."); D.I. 36 at 7-8. Courts after *Teva* have also rejected that case as unconvincing. *See, e.g.*, *Allele*, 2021 U.S. Dist. LEXIS 85347, at *16-17

[5] Sarepta relies on *UCB, Inc. v. Catalent Pharma Sols., Inc*. for the first time in its Motion despite the decision issuing in May 2021. Notably, Sarepta did not bring *UCB* to the court's attention by letter or at oral argument on its motion to dismiss in December 2021.

("[T]he Court does not find persuasive Defendants' reliance on *Teva Pharms. USA, Inc. v. Sandoz Inc*."); *ISIS Pharms.*, 2014 U.S. Dist. LEXIS 26148, at *33 n.7 ("Having considered *Teva*, this Court disagrees with its limited reading of *Proveris* and its complete rejection of *PSN Illinois*."). Because *Teva* is a single outlier in the line of consistent decisions from the Federal Circuit and district courts, it cannot serve as a substantial ground for difference of opinion. Regardless, even when "[t]here may be grounds for difference of opinion, and room for appellate clarification, on the issues identified by Defendants," denial of interlocutory appeal is still proper. *CFL Techs. LLC v. Osram Sylvania, Inc.*, No. 1:18-cv-01445-RGA, 2019 U.S. Dist. LEXIS 142718, at *4 (D. Del. Aug. 22, 2019) (Andrews, J.); *see also In re BSA*, 2021 U.S. Dist. LEXIS 58837, at *14 (noting that a "substantial ground for difference of opinion . . . calls for more than mere disagreement.").

Sarepta also attempts to manufacture tension between prior Federal Circuit opinions on the Safe Harbor where none exists. Mot. at 12-13. The cases it contends that are in tension, *Proveris*, *AbTox*, and *Momenta I*, dealt with distinct questions regarding different parts of Section 271(e)(1). For example, while the court in *Momenta I* focused on whether the defendant's activities were "solely for purposes reasonably related to the development and submission" of information to the FDA, as Sarepta recognizes, *see Momenta Pharms. v. Amphastar Pharms.*, 686 F.3d 1348, 1357 (Fed. Cir 2012) ("*Momenta I*"), the court in *AbTox* faced the question of whether Class II medical devices constituted "patented inventions" under the statute. *See* 122 F.3d at 1027. *Proveris* dealt with an entirely different question altogether, whether the protections of Section 271(e)(1) extended to the use of a patented product that was not itself subject to FDA premarket approval. *See* 536 F.3d at 1265. There is nothing inconsistent in these decisions, all of which consistently address the meaning and applicability of the terms and phrases used in Section 271(e)(1).

Sarepta next attempts to manufacture tension between the *Proveris* court's reference to the need for "symmetry" between the Section 271(e)(1) Safe Harbor and Section 156 patent term extension provisions, and *Eli Lilly*. Mot. at 12-13. But when *Proveris* was decided by the Federal Circuit, that court had already addressed an earlier case, *AbTox*, in which the patented product was not afforded the symmetry between Section 271(e)(1) and Section 156. Specifically, because the Class II medical device at issue in *AbTox* required FDA premarket approval, it was held to be subject to the Safe Harbor even though it was not eligible for a Section 156 patent term extension. *See* 122 F.3d at 1029 ("[T]he Supreme Court commands that statutory symmetry is preferable but not required."). That the Federal Circuit in *Proveris* recognized the desirability of statutory symmetry between Section 271(e)(1) and Section 156, as defined by *Eli Lilly*, does not create any tension between *Proveris* and *Eli Lilly*, especially when the Federal Circuit found the Safe Harbor applied to the patented product in *AbTox* notwithstanding a lack of statutory symmetry. Thus, no tension or inconsistency exists in the case law on this issue, but rather a clear line drawn by prior cases that Sarepta simply does not like.

Moreover, permitting this appeal would not provide any benefit to players in the industry as Sarepta contends. Mot. at 11-12. The law regarding the meaning of a "patented invention" in Section 271(e)(1) is settled, and there is sufficient guidance to companies on what products and conduct are protected by the Safe Harbor, and when licensing a patent may be necessary. That Sarepta failed to follow this clear line and is unhappy with the result is not a reason to grant interlocutory review.

C. Sarepta's Appeal Would Not Materially Advance the Ultimate Termination of This Litigation

Sarepta's argument that this appeal will advance the termination of this litigation and conserve judicial resources is simply not true since the allegations concerning Sarepta's

commercial activities would, in any event, have to be adjudicated. Thus, this appeal is a drain of all parties' and the Court's time and resources. "Entertaining review of an interlocutory order under § 1292(b) is appropriate only when the party seeking leave to appeal 'establishes exceptional circumstances [to] justify a departure from the basic policy of postponing review until after the entry of final judgment.'" *YPF, S.A. v. Maxus Liquidating Trust*, No. 21-mc-353-RGA, 2021 U.S. Dist. LEXIS 184133, at *5 (D. Del. Sep. 27, 2021) (Andrews, J.) (quoting *In re Del. & Hudson Ry. Co.*, 96 B.R. 469, 472-73 (D. Del. 1989), *aff'd*, 884 F.2d 1383 (3d Cir. 1989)). There are no exceptional circumstances here, and no reason exists why this case cannot follow the same process as every other lawsuit. Sarepta can appeal the Safe Harbor issue once final judgment is entered in this case.

In fact, Sarepta's interlocutory appeal, if allowed, will waste party resources, as the litigation will continue during the pending appeal. *See* 28 U.S.C. § 1292(b) ("[A]pplication for an appeal hereunder shall not stay proceedings in the district court."). Even if the Federal Circuit ultimately agrees with Sarepta, this case will proceed, wasting further resources while the parties litigate the disputed commercial marketing issues. As noted above, these issues have already been adjudged to be significant in similar litigation involving Sarepta. *See Wilson Wolf Mfg.*, 2020 U.S. Dist. LEXIS 244122, at *15. The Federal Circuit can review the question regarding the Safe Harbor on appeal following entry of the final judgment, but on a full factual record instead of at the motion to dismiss stage. To do otherwise would simply be wasteful.

V. CONCLUSION

Sarepta's motion fails to demonstrate that its allegedly controlling question of law meets the exacting standards necessary for an interlocutory appeal. For that reason, Plaintiff REGENXBIO respectfully requests that the Court deny Sarepta's motion for certification for interlocutory appeal.

Dated: February 7, 2022

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